



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/567,459

07/21/2006

Henry William Lupton

Q92794

9156

23373 7590 02/19/2010
SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

EXAMINER

DOUGHERTY, SEAN PATRICK

ART UNIT

PAPER NUMBER

3736

NOTIFICATION DATE

DELIVERY MODE

02/19/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

sughrue@sughrue.com
PPROCESSING@SUGHRUE.COM
USPTO@SUGHRUE.COM

Office Action Summary	Application No. 10/567,459	Applicant(s) LUPTON, HENRY WILLIAM	
	Examiner SEAN P. DOUGHERTY	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 76-84, 87, 88, 96 and 98-107 is/are pending in the application.
- 4a) Of the above claim(s) 81, 106 and 107 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 76-78, 81-84, 87, 88, 96 and 98-107 is/are rejected.
- 7) ☒ Claim(s) 79 and 80 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>EAST Search</u> . |

DETAILED ACTION

This is the FINAL Office action based on the 10/567459 application filed 07/21/2006.

Election/Restrictions

Claims 81 and 94 (now cancelled) have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species and group, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on 02/06/2009.

Newly added claims 106 and 107 are withdrawn, as being dependant upon withdrawn claim 81.

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Response to Amendment

The amendment(s) filed 10/07/2009 by the Applicant in response to the previous Office action mailed 04/07/2009 have been considered by the Examiner. The Examiner acknowledges:

- Claims numbered 1-107 including:

Art Unit: 3736

- Pending claim(s) 76-84, 87, 88, 96 and 98-107;
- Amended claim(s) 76-84, 87, 88 and 96;
- New claim(s) 98-107;
- Cancelled claim(s) 1-75, 85, 86, 89-95 and 97; and
- Withdrawn claim(s) 81, 106 and 107.

The Applicant's amendments have overcome the 35 U.S.C. 112 second paragraph rejections in the previous Office action of claims 78, 81-85, 90, 91 and 95 in the previous Office action.

The rejection(s) in the previous Office action of claim(s) 76, 78-80, 82-84, 86-88, 90-93 and 95 as being anticipated by Backman, et al. are maintained, however, a new interpretation of the prior art has been provided. The rejection(s) in the previous Office action of claim(s) 77, 85, 89, 96 and 97 as being unpatentable over Backman, et al. in view of Bostrom, et al. are withdrawn in response to the amended claim(s). The following reiterated and new ground(s) of rejection(s) is/are set forth below:

Claim Objections

The following claims are objected to because of the following informalities:

Claim 76 recites the limitation "and comprising an elongated core wire" at line 4 and should recite --and an elongated core wire".

Claims 79 and 80 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim(s) 76-84, 87, 88, 96, 98-107 is/are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 76, the limitation “and extending axially between a distal end for accessing the remote site” renders the claim indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. The Examiner notes it is indefinite what portion of the claimed invention the aforementioned limitation is in reference to. It is indefinite if the guide wire or the longitudinally extending axis extends “axially between a distal end for accessing the remote site”. For sake of examination, the Examiner has interpreted the aforementioned limitation to claim that the guide wire extends "axially between a distal end for accessing the remote site”.

Claim 76 is similarly rejected with regards to the limitation "a spaced apart proximal end". Examiner notes it is indefinite what portion of the claimed invention the aforementioned limitation is in reference to. It is indefinite if the guide wire or the longitudinally extending axis has a spaced apart proximal end. For sake of examination, the Examiner has interpreted the aforementioned limitation to claim that the guide wire extends has "a spaced apart proximal end”.

Art Unit: 3736

Regarding claim 76, the limitation “between a distal end” renders the claim indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. The Examiner notes it is indefinite how the central axis can extend axially between a distal end, when a distal end is a single point. There appears to be lacking a second element recited for such central axis to actually be in a “between position”. For sake of examination, the Examiner has interpreted the aforementioned limitation the claim the guide wire extends between a distal end and an element located proximal to the distal end.

Regarding claim 76, the limitation “and further defining a central major plane” and “and a central major plane” renders the claim indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. The Examiner notes it is indefinite what portion of the claimed invention is defining both the “central major plane” and “central major plane”. For sake of examination, the Examiner has interpreted that the aforementioned limitations are defined by the major and minor surfaces.

The Examiner respectfully notes that independent claims 87 and 88 contain the same and/or similar types of wording that render the claims indefinite. Applicant's assistance is requested with modifying claim language to make it definite, when a portion of limitation is recited, what portion of the claimed invention is being referenced.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

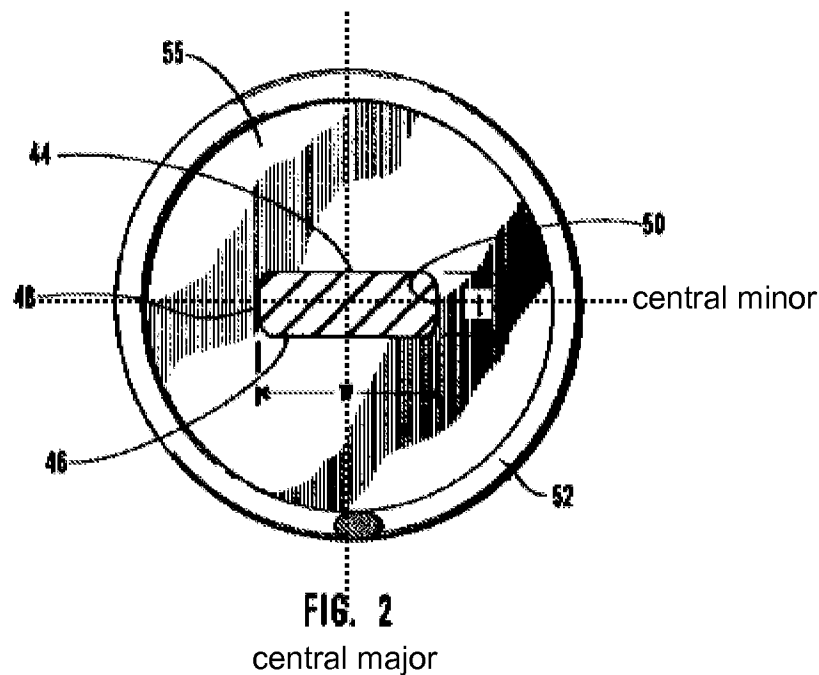
Claims 76, 78, 82-84, 87, 88 and 98-105 rejected under 35 U.S.C. 102(b) as being anticipated by US 5957865 to Backman, et al. (hereinafter “Backman”).

Regarding claims 76, 87, 88 and 99, Backman discloses:

- an elongated guide wire (10) for use in a surgical or other procedure for accessing a remote site in the body of a human or animal subject,
- the guide wire defining a longitudinally extending central axis (through the central axis of the guide wire extending from element 14 to element 58), and
- extending axially between a distal end (22) for accessing the remote site, and
- a spaced apart proximal end (14), and comprising
- an elongated core wire (see Figure 1) extending from the proximal end and terminating in a distal portion adjacent the distal end of the guide wire,
- the distal portion of the core wire being of substantially rectangular transverse cross-section (see Figure 2) defining
- a pair of spaced apart major surfaces (t), and
- a pair of spaced apart minor surfaces (w) extending between the major surfaces, and further defining

Art Unit: 3736

- a central major plane lying intermediate the major surfaces and bisecting the minor surfaces (see Figure 2, below), and
- a central minor plane lying intermediate the minor surfaces and bisecting the major surfaces (see Figure 2, below), wherein
- the distal portion of the core wire is bent into a curved configuration in the central major plane for forming an alignment portion lying in the central major plane and extending from the bend at an angle greater than zero relative to the central axis for facilitating guiding of the guide wire into a branched vessel of the subject (col. 6, ll. 37-46).



With regard to claim 88, it is noted that the device of Backman, et al. appear to be substantially identical to the device claimed, although produce by a different process, therefore the burden is upon the applicant to come forward with evidence establishing an unobvious difference between the two. In re Marosi, 218 USPQ 289 (Fed. Cir. 1983).

Regarding claims 78, 98, 100 and 101, Backman discloses where the distal portion of the core wire is of a material for retaining the distal portion in the curved configured formed by the bends. The distal portion is manually bendable in a central minor plane when at least a part of the alignment portion is bent out of the central major plane because the distal portion is established as being made of a material that is flexible in multiple positions for navigation (col. 5, lines 56-61). Backman establishes the core wire 12, which includes the distal end 22, constructed of stainless steel (col. 4, line 56).

Regarding claim 82, Backman discloses where the distal portion of the core wire is integrally formed with the core wire as best seen in Figure 1. The Examiner notes both the distal portion of the core wire and the core wire are attached and function together as a whole, therefore, they are integral.

Regarding claim 102, Backman discloses where the distal portion of the core wire is formed separately from the core wire, and is secured thereto. It is noted that the device of Backman appears to be substantially identical to the device claimed, although produce by a different process, therefore the burden is upon the applicant to come forward with evidence establishing an unobvious difference between the two. In re Marosi, 218 USPQ 289 (Fed. Cir. 1983).

Regarding claims 103-105, Backman discloses where the distal portion of the core wire terminates in a radiused bulbous portion (16) at the distal end of the guidewire for facilitating guiding of the guide wire through vessels of the subject without damaging the vessels. The bulbous portion defines the distal end of the guidewire as it is located

Art Unit: 3736

at the distal end of the guidewire and is radiused, therefore forming a hemispherical distal end.

Regarding claims 83 and 84, Backman discloses where the guide wire comprises a sleeve (52/38) extending from the bulbous portion in a proximal direction along the core wire beyond the distal portion of the core wire, one end of the sleeve being secured to the bulbous portion of the guide wire, and the other end of the sleeve being secured to the core wire (best seen in Figure 1). Backman discloses where the distal end of the sleeve is of a radiopaque material (col. 6, ll. 57-60).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 77 and 96 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,957,865 to Backman et al. (hereinafter "Backman"), in view of EP 0 773 037 to Bostrom et al. (hereinafter "Bostrom", cited in the IDS).

Regarding claims 77 and 96, Backman discloses the limitations of the claims as stated above and that the distal rectangular end 22 may be bent into a specific angle chosen in accordance to a particular use (col. 6, ll. 36-46). Backman does not expressly disclose where the angle is in the range of 30 to 90 degrees. Bostrom teaches a inner stylet having a non-circular cross-section (col. 3, lines 25-26) that is pre-bent to one side in a direction (col. 3, ll. 36-40) that can cover an angle in the range of 30 to 90 degrees (col. 4, ll. 19-24). One having an ordinary skill in the art at the time the invention was

Art Unit: 3736

made would have found it obvious to modify the guidewire of Backman to comprise the pre-bent configuration in the range of 30 to 90 degrees of Bostrom as the predictable result of employing a guidewire within a body with a pre-bent configuration at specified angles would ensue. Therefore, a skilled artisan would have found the combination of Backman and Bostrom obvious.

Response to Arguments

Applicant's arguments with respect to claim(s) 76, 78-80, 82-84, 86-88, 90-93 and 95 as being anticipated by Backman, et al. have been considered but are moot in view of the new ground(s) of rejection. The Examiner notes that a new interpretation of Backman, et al. has been provided above that is deemed to meet the claimed limitations. Specifically, the Examiner notes that the guidewire may be bent into a curved configuration in the central major plane.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

Art Unit: 3736

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SEAN P. DOUGHERTY whose telephone number is (571)270-5044. The examiner can normally be reached on Monday-Friday, 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sean P. Dougherty/
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736